Sub E2

7. (Amended) A method for detecting a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the first support and bound target polynucleotide from the sample;

(c) amplifying *in vitro* the separated target polynucleotide; and

(d) detecting the presence of the amplified target polynucleotide as indicative of the presence of the target polynucleotide in said sample.

Sub E3

11. (Amended) The method of claim **10** wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase [or Qβ replicase].

Sub E4

13. (Amended) The method of claim **7** wherein the amplified target polynucleotide is contacted with a label, and the presence of the target polynucleotide in the sample is indicated by detection of said label.

14. (Amended) The method of claim **7** wherein the amplified target polynucleotide is contacted with a labeled probe, and the presence of the target polynucleotide in the sample is indicated by detection of said labeled probe.

Sub E5

16. (Amended) The method of claim **15** wherein the [amplified target polynucleotide is contacted with] second support includes a labeled probe, and the presence of the target polynucleotide in the sample is indicated by detection of said labeled probe.

Sub E6

19. (Twice amended) A method for detecting a target polynucleotide contained in a sample comprising the steps of:

(a) contacting the sample with a first support which binds to the target polynucleotide;

(b) substantially separating the first support and bound target polynucleotide from the sample;

(c) amplifying *in vitro* the [sample] separated target polynucleotide with a DNA polymerase;

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(d) contacting the amplified target polynucleotide with a second support which binds to the amplified target polynucleotide and also with a labeled probe which binds to the amplified target polynucleotide; and

(e) detecting the presence of the [amplified target polynucleotide] labeled probe as indicative of the presence of the target polynucleotide in said sample.

20. (Amended) A kit for detecting a target polynucleotide contained in a sample comprising:

(a) means for substantially separating the target polynucleotide from the sample prior to amplification of the target polynucleotide;

(b) means for amplifying *in vitro* the separated target polynucleotide;

(c) means for binding the amplified target polynucleotide to a solid support; and

(d) means for labeling the amplified target polynucleotide.

21. (Amended) The kit of claim **20** wherein:

(a) the means for substantially separating the target polynucleotide from the sample include a first support;

(b) the means for amplifying *in vitro* the separated target polynucleotide include a polymerase;

(c) the means for binding [that] the amplified target polynucleotide to a solid support include a capture probe which binds to the solid support and to the amplified target polynucleotide; and

(d) [a detector probe] the means for labeling the amplified target polynucleotide include a detector probe.

22. (Amended) The kit of claim **21** further comprising a [capture] probe which binds to the first support and to the target polynucleotide.

24. (Amended) A kit for amplifying a target polynucleotide contained in a sample comprising:

(a) means for substantially separating the target polynucleotide from the sample prior to amplification of the target polynucleotide; and

(b) means for amplifying *in vitro* the separated target polynucleotide.

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25. (Amended) The kit of claim **24** wherein:

(a) the means for substantially separating the target polynucleotide from the sample [includes] include a support which binds to the target polynucleotide; and

(b) the means for amplifying *in vitro* the separated target polynucleotide [includes] include a polymerase.

26. (Amended) The kit of claim **25** wherein:

(a) the polymerase is a DNA polymerase; and

(b) the means for substantially separating the target polynucleotide from the sample [includes] include a probe which binds to the target polynucleotide and the support.

27. (Amended) A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with reagent comprising a first nucleic acid probe which binds to the target polynucleotide to form a probe-target complex;

(b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;

(c) substantially separating the support and bound probe target complex from the sample medium;

(d) contacting the support and bound probe-target complex with a second medium;

(e) releasing the probe-target complex into the second medium;

(f) substantially separating the support from the second medium; and

(g) amplifying *in vitro* the target polynucleotide present in the second medium.

28. (Amended) A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with reagent comprising a first nucleic acid probe which binds to the target polynucleotide to form a probe-target complex;

(b) contacting the sample medium with a support which binds to the first nucleic acid probe of the probe-target complex;

(c) substantially separating the support and bound probe-target complex from the sample medium;

(d) contacting the support and bound probe-target complex with a second medium;

(e) releasing the probe-target complex into the second medium;

(f) substantially separating the support from the second medium;

(g) amplifying *in vitro* the target polynucleotide present in the second medium; and

(h) detecting the presence of the target polynucleotide in the second medium as indicative of the presence of the target polynucleotide in said sample.

30. (Amended) The method for detecting a target polynucleotide of claim **29** wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase[, or Qβ replicase].

34. (Amended) A method for amplifying a target polynucleotide contained in a sample medium comprising the steps of:

(a) contacting the sample medium with a support and a probe which binds to the target polynucleotide and the support;

(b) substantially separating the support and bound probe and target polynucleotide from the sample medium;

(c) contacting the support and bound probe and target polynucleotide with a second medium;

(d) releasing the target polynucleotide into the second medium;

(e) substantially separating the support and bound probe from the second medium;

(f) amplifying *in vitro* the target polynucleotide present in the second medium.

35. (Amended) The method for amplifying a target polynucleotide of claim **34** wherein the target polynucleotide is amplified with a polymerase.

36. (Amended) The method for amplifying a target polynucleotide of claim **35** wherein the polymerase is a DNA polymerase, an RNA polymerase, or a transcriptase [or Qβ replicase].

38. (Amended) A method for detecting a target polynucleotide contained in a sample medium comprising the steps of:

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(a) contacting the sample medium with a support and probe which binds to the target polynucleotide and the support;

(b) substantially separating the support and bound probe and target polynucleotide from the sample medium;

(c) contacting the support and bound probe and target polynucleotide with a second medium;

(d) releasing the target polynucleotide into the second medium;

(e) substantially separating the support and bound probe form the second medium;

(f) amplifying *in vitro* the target polynucleotide present in the second medium; and

(g) detecting the presence of the amplified target polynucleotide in the second medium as indicative of the presence of the target polynucleotide in said sample.

Please amend claims 42, 44, 46, 48, 50, and 52 (which had been introduced in the Preliminary Amendment and which differ from those claims as set forth on the attached appendix) as follows:

42. (Amended) The amplification method of claim 1 wherein the amplification is linear or exponential.

44. (Amended) The amplification method of claim 1 wherein the target polynucleotide is amplified with a polymerase and at least one oligonucleotide primer.

46. (Amended) The amplification method of claim 1 wherein the target polynucleotide is amplified with more than one polymerase.

48. (Amended) The detection method of claim 7 wherein the amplification is linear or exponential.

50. (Amended) The detection method of claim 7 wherein the target polynucleotide is amplified with a polymerase and at least one oligonucleotide primer.

52. (Amended) The detection method of claim 7 wherein the target polynucleotide is amplified with more than one polymerase.

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Please add new claims 64-82 as follows:

64. The method of claim **1** wherein the separated target polynucleotide is amplified non-specifically with random primers.

65. The method of claim **1** wherein the separated target polynucleotide is amplified specifically with specially tailored primers.

66. The method of claim **7** wherein the separated target polynucleotide is amplified non-specifically with random primers.

67. The method of claim **7** wherein the separated target polynucleotide is amplified specifically with specially tailored primers.

68. The amplification kit of claim **25** wherein the means for amplifying the separated target polynucleotide include means for amplifying the target polynucleotide non-specifically with random primers.

69. The amplification kit of claim **25** wherein the means for amplifying the separated target polynucleotide include means for amplifying the target polynucleotide specifically with specially tailored primers.

70. The method of claim **9** wherein the probe first binds with the target polynucleotide by hybridizing to a specific sequence in the target polynucleotide, and then binds to the first support.

71. The method of claim **70** wherein the separated target polynucleotide is amplified non-specifically with random primers.

72. The method of claim **70** wherein the separated target polynucleotide is amplified specifically with specially tailored primers.

73. The method of claim **72** wherein the sample is a clinical sample.

74. The method of claim **73** wherein the probe comprises a nucleotide sequence specific to a complementary nucleotide sequence in the target polynucleotide and a homopolymeric tail sequence.

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76. The method of claim 74 wherein the support comprises a homopolymeric tail complementary to the homopolymeric tail of the probe.

76. A kit for detecting a target polynucleotide contained in a sample comprising:

(a) means for substantially separating the target polynucleotide from the sample prior to amplification of the target polynucleotide;

(b) means for amplifying *in vitro* the separated target polynucleotide; and

(c) means for detecting the presence of the amplified target polynucleotide as indicative of the presence of the target polynucleotide in the sample.

77. The detection kit of claim **76** wherein:

(a) the means for substantially separating the target polynucleotide from the sample include a first support and a probe that binds to both the first support and the target polynucleotide;

(b) the means for amplifying *in vitro* the separated target polynucleotide include a polymerase; and

(c) the means for detecting the presence of the amplified target polynucleotide include a detector probe.

78. The detection kit of claim **77** wherein the means for substantially separating the target polynucleotide from the sample includes a first support that binds to the target polynucleotide via a probe.

79. The detection kit of claim **78** wherein the means for substantially separating the target polynucleotide from the sample include a probe that first binds to the target polynucleotide by hybridizing to a specific sequence in the target polynucleotide, and then binds to the first support.

80. The detection kit of claim **79** wherein the means for amplifying the separated target polynucleotide include means for amplifying the target polynucleotide non-specifically with random primers.

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81. The detection kit of claim **79** wherein the means for amplifying the separated target polynucleotide include means for amplifying the target polynucleotide specifically with specially tailored primers.

82. The detection kit of claim **81** wherein the sample is a clinical sample.

REMARKS

Reissue Applications

In accordance with paragraphs 1 and 2 of the Office Action, the Patent Owner submitted on February 21, 2002, a Notice of Related Litigation, which addresses arguments made in litigation by the Protestor Gen-Probe concerning the patentability of the original claims of the patent for which reissue is sought. On February 21, 2002, the Patent Owner also submitted a Supplemental Information Disclosure Statement, which identifies references not already of record that Gen-Probe has relied upon in support of its arguments concerning the patentability of those claims.

Consent of Assignee and Offer to Surrender

In paragraph 6 of the Office Action, the application is objected to under 37 C.F.R. 1.172(a) on the grounds that the assignee has not established its ownership interest in the patent for which reissue is sought. On February 20, 2002, the Patent Owner submitted a Request for Recordation of Assignment of the '338 patent from Amoco Corporation to Vysis, Inc. to establish that Vysis, Inc. is the proper assignee. That Assignment has now been recorded at Reel 012407, Frame 200.

Paragraph 7 of the Office Action notes that the original patent, or a statement as to loss or inaccessibility of the original patent, must be received before the reissue application can be allowed, pursuant to 37 C.F.R. 1.178. The Patent Owner hereby submits the original patent to fulfill this requirement.

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